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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,478	10/07/2003	Steven P. Adams	14937.0003 C2/B180 CIP DI	6640
53063 7590 05/28/2008 STEPTOE & JOHNSON LLP 1330 CONNECTICUT AVE., NW WASHINGTON, DC 20036			EXAMINER AULAKH, CHARANJIT	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 05/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/679,478	Applicant(s) ADAMS ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 3,4 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 20-22 is/are rejected.
- 7) ☒ Claim(s) 1,2,5-10,14-17 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/26/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on Feb. 26, 2008, the applicants have amended claims 1, 17 and 19-22.

2. Claims 1, 2, 5-10 and 14-22 are pending in the application. Claims 3, 4 and 11-13 remain withdrawn from further consideration as being directed to non-elected invention.

Response to Arguments

3. Applicant's arguments filed on Feb. 26, 2008 have been fully considered but they are not persuasive regarding enablement rejection of claims 18 and 20-22. The applicants have amended claims to overcome all other rejections. In regard to enablement rejection of instant claims 18 and 20-22, the applicants did not address the rejection of claim 18 at all in their response. As stated clearly in the last office action, there is no teaching in the specification or prior art that VLA4-mediated cell adhesion will be maintained in the presence of hundreds of thousands of other drugs mentioned in instant claim 18. The combination may actually compromise their inhibitory effect due to drug interaction. In regard to enablement rejection of claims 20-22, the examiner does not agree with the applicants arguments that the specification is enabling for treating these disease conditions listed in instant claims 20-22. The applicants argue that specification on pages 141-143 demonstrates efficacy of instant compounds in mouse contact hypersensitivity and sheep allergic response assays. It is not true. There is no teaching of even a single compound which was shown to be effective in these assays. The applicants just mention that the inhibitors of this invention caused significant inhibition in these assays. The applicants need to submit these data in an affidavit form

Art Unit: 1625

showing inhibition by specific compounds since they seem to have these data according to the specification. Also, are these two assays well known animal models of every known inflammatory disease, immune or autoimmune disease, asthma, psoriasis, multiple sclerosis, diabetes etc.? Alternatively, applicants need to provide prior art references showing well established utility of VLA4-mediated cell adhesion inhibitors in disease conditions listed in claims 20-22.

4. In claim 17, line 2, the applicants are suggested to delete ---- or ----after for.

Conclusion

5. Rejection of claims 18 and 20-22 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

6. Claims 1, 2, 5-10 and 14-22 are objected for containing non-elected subject matter.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625